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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,222	11/20/2003	Fred H. Burbank	R0368-03100	9030
7590	03/31/2006		EXAMINER	
Edward J. Lynch DUANE MORRIS LLP One Market Spear Tower, Suite 2000 San Francisco, CA 94105			POUS, NATALIE R	
			ART UNIT	PAPER NUMBER
			3731	
DATE MAILED: 03/31/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No. 10/718,222	Applicant(s) BURBANK ET AL.	
	Examiner Natalie Pous	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 35-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7 and 9-34 is/are rejected.
- 7) ☒ Claim(s) 5 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/22/04, 5/26/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>10/04/04, 1/31/05, 8/05/05</u> .       |

**DETAILED ACTION**

***Election/Restrictions***

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species 1: inflatable curtain occlusion means

Species 2: hydraulic occlusion means

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 4-8, 13: species 1

Claims 35-42: species 2

The following claim(s) are generic: 1-3, 9-12, 14-34.

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The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the two species provide for two materially different actuating mechanisms for the extendible pressure applicators.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

2. During a telephone conversation with Edward Lynch on 3/23/06 a provisional election was made without traverse to prosecute the invention of species 1, claims 4-8 and 13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 35-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Specification***

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it utilizes the phrase "the invention." The word invention should be avoided in the abstract. Further, the abstract exceeds the 150 word limit. Correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 3, 4, 6, 7, 9-15, 20-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al. (US 2002/0165579) in view of Nagel (US 2400251).

Burbank teaches an intravaginal uterine artery occlusion device comprising the following:

- an elongated shaft (202) which has a distal end,
- a cervical receptacle (204) which is secured to the distal end of the elongated shaft, which has an interior configured to receive at least part of a female patient's uterine cervix and which has at least one pressure applying surface (206, 208) to facilitate occlusion of the patient's uterine artery.

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- wherein cervical receptacle (204) is disposed about the patient's uterine cervix when the pressure applying surface (206, 208) is distally extendable to apply pressure to the patient's vaginal fornix (fig. 9b).
- wherein the pressure applying surface is part of a distally extendable curtain (410) which has a proximal end secured to the cervical receptacle and a distal end secured to the pressure applying surface.
- wherein the at least one extendable curtain is cylindrically shaped (par. 51).
- a pair of opposed extendable curtains (par 51, relating to embodiment 250), with each curtain having a proximal end secured to the cervical receptacle and a distal end secured to a pressure applying surface.
- wherein the leading edge has a blood flow sensor (302i) to facilitate location of the patient's uterine artery
- wherein the Doppler ultrasound sensor is configured to sense ultrasound energy having a frequency of about 8 MHz (par. 48).
- wherein at least one blood flow sensor is disposed on the leading edge of the cervical receptacle and has a sensing direction distally away from the leading edge of the cervical receptacle to facilitate detection of the patient's uterine artery (fig. 7a).
- wherein the interior of the receptacle is configured to receive the patient's cervix and part of the patient's vaginal fornix so that the leading edge of the receptacle applies sufficient pressure to the vaginal fornix to occlude the patient's uterine artery (par. 17).

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- wherein the cervical receptacle has a lowered anterior lip (210, 212), which facilitates deploying the receptacle about the patient's uterine cervix
- The device of claim 1 wherein the pressure applying surface is part of an occlusion bar (206, 208).
- Wherein the device comprises a plurality of sensors (fig. 7a).
- wherein the uterine artery remains occluded by pressure applied by the leading edge of the cervical receptacle for a limited time ranging from about 0.2 to about 24 hours and more specifically, from about 0.5 to about 16 hours (par. 72 as incorporated by U.S. application #09/556,934)

Burbank fails to disclose:

Wherein the elongated shaft has an inner lumen configured to be interconnected to a vacuum source and extending to the distal end;

wherein the interior of the cervical receptacle is configured to be in fluid communication with the inner lumen in the shaft

Nagel teaches a gynecological device wherein Wherein the elongated shaft has an inner lumen configured to be interconnected to a vacuum source and extending to the distal end; and the interior of the cervical receptacle is configured to be in fluid communication with the inner lumen in the shaft (see fig. 1 and claim 2) in order to draw the cervix into the cavity (fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Burbank with an inner



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lumen to be connected to a vacuum source as taught by Nagel in order to facilitate drawing the cervix into the cavity of the device.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 16, 17, 18, 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagel (US 2400251).

Regarding Claim 1 Nagel teaches a gynaecological instrument suitable to be used as an intravaginal uterine artery occlusion device, comprising:

an elongated shaft (16) which has a distal end, an inner lumen configured to be interconnected to a vacuum source (claim 2) and extending to the distal end; and a cervical receptacle (24) which is secured to the distal end of the elongated shaft, which has an interior configured to receive at least part of a female patient's uterine cervix and which has at least one pressure applying surface (28) to facilitate occlusion of the patient's uterine artery.

Regarding Claim 2, Nagel teaches the device of claim 1 wherein the interior of the cervical receptacle is configured to be in fluid communication with the inner lumen (52) in the shaft

Regarding Claim 16, Nagel teaches the device of claim 1 wherein the cervical receptacle has an elongated cervical sound (36) within the interior thereof configured to be guided into a female patient's cervical canal to thereby position the receptacle about the exterior of the patient's cervix (fig. 1).

Regarding Claim 17, Nagel teaches the device of claim 16 wherein the elongated cervical sound is provided with a rounded non-traumatic distal tip (44).

Regarding Claim 18, Nagel teaches the device of claim 1 wherein the cervical receptacle has at least one groove in an inner surface (Column 1, proximate lines 50-55 to Column 2, proximate lines 1-3).

Regarding Claim 19, Nagel teaches the device of claim 17 wherein the at least one groove is parallel to a central axis of the receptacle (Column 1, proximate lines 50-55 to Column 2, proximate lines 1-3).

Regarding Claim 21, Nagel teaches the device of claim 1 wherein the cervical receptacle has a lowered anterior lip, which facilitates deploying the receptacle about the patient's uterine cervix (Column 1, proximate lines 50-55 to Column 2, proximate lines 1-3).

#### ***Allowable Subject Matter***

7. Claims 5 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***


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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP  
3/24/06

  
(JACKIE) TAN-LYEN HO  
PRIMARY EXAMINER  
3/28/06